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Drug manufacturer Sanofi has sued the federal government for information about contracts between covered entities and contract pharmacies.

Sanofi Sues HHS, HRSA for Contract Details Between Covered Entities, Pharmacies

June 13, 2024 Rich Daly, Editor in Chief

French drugmaker Sanofi recently filed suit against federal agencies seeking details from contracts between 340B covered entities and outside pharmacies. One provider attorney raised concerns the information will be used to challenge a key pillar of contract pharmacy use.

The May 31 lawsuit (<https://340breport.com/wp-content/uploads/2024/06/Sanofi-FOIA-case.pdf>) filed in the U.S. District Court for the District of Columbia by Sanofi against the Department of Health and Human Services (HHS) and the Health Resources and Services Administration (HRSA) sought to force compliance with a previously filed Freedom of Information Act (FOIA) request.



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The company said the information it sought from covered entities' contracts with outside pharmacies is "evidence of [federal officials'] ongoing refusal to enforce the 340B statute's prohibition on diverting 340B-priced drugs to persons who are not the covered entity's patient."

"With this information, Sanofi would be able to expose HRSA's failure to enforce the 340B statute's prohibition on diversion, more effectively defend itself against covered entities' claims alleging violations of the 340B statute, and consider bringing diversion claims against covered entities," said the lawsuit.

Two ways HRSA collects such contracts are quarterly checks of a random sample of 5% of new contract pharmacy arrangements to verify various elements of each contract, and through the 200 annual HRSA audits of covered entities, which require verification of certain provisions of pharmacy contracts, according to a report (<https://www.gao.gov/assets/gao-23-106095.pdf>) by the Government Accountability Office.

Sanofi said the contracts are needed to prove whether covered entities are retaining title to 340B-priced drugs shipped to contract pharmacies. The suit cited a May 21 decision (<https://340breport.com/appeals-court-approves-drugmakers-federal-340b-contract-pharmacy-restrictions-but-leaves-open-possibility-of-enforcement-against-stricter-policies/>) by the U.S. Court of Appeals for the District of Columbia that said HRSA's guidance said covered entities "must retain title to the drugs" shipped to contract pharmacies.

In a response to questions from 340B Report, a Sanofi spokesperson said the company "remains concerned with the waste and abuse within the 340B Program. Contract pharmacies, in particular, are a major source of diversion and duplicate discounts. Meanwhile, the continued misuse of 340B by covered entities and their

contract pharmacies negatively impacts the larger healthcare system and patients. Our aim is to ensure a strong future for the 340B Program, and bringing more transparency to the relationship between covered entities and contract pharmacies is a step in that direction.”

HHS and HRSA did not respond to requests for comment.

Lawsuit Origins

Sanofi’s original FOIA request in July 2021 came after HHS issued a since-withdrawn (<https://340breport.com/breaking-hhs-withdraws-340b-contract-pharmacy-advisory-opinion-and-becerra-appoints-340b-dispute-resolution-board-members/>) advisory opinion that said the 340B statute required manufacturers to deliver covered drugs to any contract pharmacies with which a covered entity chooses to partner. That advisory opinion was followed by HRSA sending enforcement letters (<https://340breport.com/breaking-hrsa-to-six-drug-makers-your-340b-contract-pharmacy-policies-are-illegal-resume-offering-340b-pricing-immediately/>) to manufacturers that they were required to deliver their 340B-priced drugs to all contract pharmacies without any restrictions.

Sanofi and other manufacturers challenged HRSA’s enforcement letters in separate suits and prevailed in separate decisions by the D.C. Circuit Court of Appeals and the U.S. 3rd Circuit Court of Appeals (<https://340breport.com/third-circuit-court-rules-for-drugmakers-in-340b-contract-pharmacy-cases/>) in Philadelphia. A third such 340B contract pharmacy case, *Lilly v. Becerra* (<https://340breport.com/wp-content/uploads/2022/04/Document.pdf>), is before the U.S. 7th Circuit Court of Appeals in Chicago. A decision is expected soon.

“Sanofi’s request sought information only regarding the agency relationships between contract pharmacies and covered entities and which party maintains title over the drugs,” said the new lawsuit.

“Sanofi sought this information to support or refute HHS’s assertions in the Advisory Opinion and to better understand whether covered entities’ arrangements with contract pharmacies comply with the 340B statute,” said the lawsuit.

HRSA initially said it could respond to some requests in the FOIA by releasing data previously released as part of earlier FOIA lawsuit.

A July 2021 lawsuit (<https://340breport.com/law-firm-sues-hrsa-over-foia-request-for-340b-contract-pharmacy-documents/>) in federal district court in Washington, D.C., by the law firm Latham & Watkins sought to enforce a FOIA against HHS and HRSA for information needed to represent United Therapeutics in that manufacturer's contract pharmacy lawsuit. Among information sought were "certifications that covered entities have filed with HRSA since March 2010 about use of 'contract pharmacies' and their compliance with the 340B program's regulatory requirements." That FOIA case was dismissed in April 2023 after HHS released 8,127 pages—according to the latest lawsuit—to United Therapeutics.

But in follow up communications with Sanofi, HRSA declined to release any information citing FOIA exemption 4, which protects "trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential," according to a Justice Department descriptor page (https://www.justice.gov/archive/oip/foia_guide09/exemption4.pdf).

Sanofi responded that it "is not seeking the financial terms in the pharmacy contracts or, for that matter, even the identities of the contracting parties. It seeks only the portions of those contracts that address compliance with applicable law—including who retains title to 340B-priced drugs," said the lawsuit.

'The Death of Contract Pharmacy Arrangements'

Emily Cook, a partner at McDermott Will & Emery who represents covered entities, questioned the stated purpose of the FOIA request and the related lawsuit—to confirm that 340B covered entities do not retain title to drugs shipped to contract pharmacies.

"In reality, the fact that they can articulate the operation of the replenishment model in such detail reveals that they already know the answer to the question they claim only the agreements can provide," said Cook. "They explicitly state: 'This method for distributing prescription drugs—known as the replenishment model—is a main driver of waste and abuse in the 340B Program,' suggesting that the end goal here is to get a court to find that the replenishment model is unlawful."

Cook said that, in order for the replenishment model to function, "the title to 340B drugs transfers to the contract pharmacy at the time it is taken into inventory."

"If the 340B covered entity retained title through to the point of dispensing it would not be a replenishment model," Cook said. "It would result in the replenished drugs only being eligible to be dispensed to a 340B-eligible patient of the covered entity, which is a physical inventory model."

Cook said the FOIA request indicates manufacturers plan to allege through lawsuits and through the soon-to-launch administrative dispute resolution process that the replenishment model results in 340B drug diversion.

"I would also not be surprised if Sanofi wants the agreements to identify other provisions or operations of contract pharmacy arrangements that they could challenge in an attempt to get a court to rule that the replenishment model can't be used for 340B contract pharmacy arrangements, which would effectively be the death of contract pharmacy arrangements," Cook said.



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(<https://340breport.com/2024/05/>)May (64) (<https://340breport.com/2024/05/>)

(<https://340breport.com/2024/04/>)April (68) (<https://340breport.com/2024/04/>)

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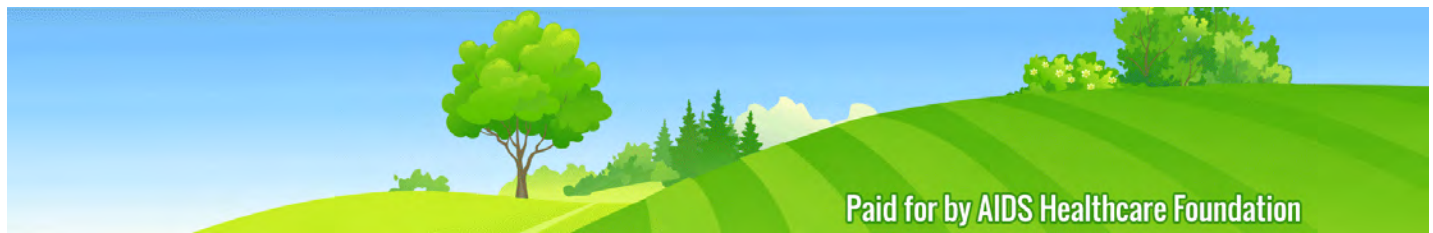


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